

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS LLC,	:	
et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 13-236-RGA
	:	
PERRIGO COMPANY, et al.,	:	
	:	
Defendants.	:	

MEMORANDUM ORDER

On July 23, 2014, I denied Perrigo's motion for leave to file an amended answer including inequitable conduct allegations. (D.I. 153). On August 20, 2014, Plaintiffs filed an amended complaint. (D.I. 164). Perrigo filed an answer – 293 pages long – to the amended complaint on September 29, 2014. (D.I. 185). Perrigo filed a separate answer – a modest 243 pages long – to a separate complaint. (D.I. 186). (The record is confusing because of the consolidation of a number of cases.). Plaintiffs have responded with a motion to dismiss Perrigo's inequitable conduct counterclaims and defenses. (D.I. 201). It has been briefed. (D.I. 202, 221, 235).

While Plaintiffs complain about Perrigo raising defenses that were previously rejected by me, I do not see why Perrigo could not raise its defenses in response to new pleadings (including newly asserted patents) by Plaintiffs. I ruled before that Perrigo could not amend its pleadings to assert inequitable conduct. Perrigo does not need leave to file these answers and counterclaims; indeed, it has to file answers. It may be that in the end, the issue for me is the same – whether

Perrigo has stated a claim – but its new pleadings are not verbatim¹ recitations of its old pleadings, and the different procedural posture gives Perrigo a plausible reason for a second try.

That being said, Perrigo's recitation of facts makes for impenetrable reading. The allegations of inequitable conduct are about two and one-half times the length of a principal opening brief in the courts of appeals. *See* Fed. R. App. P. 28.1(e)(2)(A)(i) (14,000 word limit). It does not appear that there was any effort made to tell a comprehensible story.² Perrigo's attorneys, apparently aware that the inequitable conduct allegations are nearly incomprehensible, try to rehabilitate the pleading with a mixture of underlining and the use of bold, italic, and bold italic fonts. It is as if Perrigo has dumped a pile of garbage in front of me, saying that there is a golden ring in the garbage, while directing my attention to various flashing colored lights, the point of which is unexplained.

Nevertheless, I turn to Perrigo's briefing to try to understand the inequitable conduct allegations. The briefing has the same idiosyncratic combination of underlining and the use of various fonts to try to make its message clearer. In order to support its arguments, it cites to the answer, although the value of the citations is somewhat diminished when pages and pages of paragraphs are cited to support a single sentence.³ Nevertheless, the crux of Perrigo's argument is summarized in its brief at pages 14-18. (D.I. 221 at 20-24). I now turn to it.

“An individual associated with the filing and prosecution of a patent application commits

¹ By my count, Perrigo has reduced its verbiage on inequitable conduct from about 55,000 words to about 37,500 words. (D.I. 185, where the inequitable conduct allegations go from about page 91 to page 278). As Plaintiffs admit, some editing has been done. (D.I. 202, p. 3).

² By contrast, earlier today Perrigo made an admirably “to the point” *Markman* presentation.

³ For reasons that are not obvious to me, Perrigo's sealed brief cites to the redacted versions of its answers.

inequitable conduct when he or she (1) makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the PTO; (2) with the specific intent to deceive the PTO. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).” *Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715, *5 (D. Del. Feb. 3, 2012), *adopted*, 2012 WL 749378 (D. Del. Mar. 1, 2012). Perrigo’s pleadings and arguments must be evaluated in light of this standard.

Four individuals are named as having committed inequitable conduct.

The first is an expert witness – Dr. Weiner – hired by Plaintiffs. The allegations against him are summarized by seven bulleted points. (D.I. 221 at 21).⁴ Three of the bulleted points (## 1, 3, and 5) are unexceptional. Perrigo cites 22 paragraphs for the proposition that Dr. Weiner “knew [his] affidavits . . . contained false and misleading statements.” (D.I. 221 at 21, citing D.I. [185], ¶¶ 403-24). The essence of these paragraphs are allegations that: (1) Dr. Weiner submitted two affidavits to the PTO which discussed data from Example 1 of the patent then being prosecuted; (2) the data came from an *in vitro* study; (3) Dr. Weiner claimed that the data showed unexpectedly therapeutic results in treating a human; (4) thus meaning that Dr. Weiner was asserting that *in vitro* studies had value in predicting *in vivo* results; and (5) in contrast with the last allegation, Dr. Weiner is on record, both before and after the submission of the two affidavits at issue, as stating that *in vitro* tests are neither predictive nor correlative of *in vivo* results.

Perrigo quotes Dr. Weiner’s actual (supposedly false or misleading) statements in ¶ 403.

⁴ There is also a diversionary argument that Dr. Weiner failed “to disclose his extensive employment for Plaintiffs.” (D.I. 221, at 16). Perrigo does not then cite where its allegations about this are in the Answer. I do not see any basis for concluding that Dr. Weiner’s involvement in the “1% Antitrust Litigation” or “1% Patent Litigation” as being something that was independently required to be disclosed.

He stated that the data “are an indication” of efficacy. (D.I. 185, ¶403(a)). He further stated that “[i]t is also possible that at some level” [the therapeutic benefits would end]. (D.I. 185, ¶403(b)). It seems to me that, contrary to the use of the word “false,” there is no allegation of falsity here. How could there be, given the hesitancy used in expressing Dr. Weiner’s positions? There is barely even an allegation that Dr. Weiner’s argument is “misleading.” Rather, the argument is that he should not have used the *in vitro* studies to make an argument that the results disclosed in the patent at issue were “surprising and unexpected.” (D.I. 185, ¶403(c)). It is not alleged that Dr. Weiner said one place, *In vitro* results do not predict *in vivo* results, and said to the PTO, *In vitro* results predict *in vivo* results. The argument is that what he said to the PTO had the unstated premise that *in vitro* results predict *in vivo* results. It seems to me that stating that *in vitro* results provide “indications” or “possibilities” about *in vivo* results is not the same thing as saying that they predict the results. One is significantly more tentative than the other. Further, common sense says that *in vitro* studies can provide “indications” or “possibilities” for *in vivo* studies. Why else would they be done? Therefore, I do not think Perrigo has plausibly alleged a false or misleading or deceptive statement by Dr. Weiner in his affidavits.

It follows that the fourth bulleted point fails, as it essentially says that Dr. Weiner did not disclose materials (D.I. 185, ¶¶ 416-31) that would support Perrigo’s argument that the affidavits were false. The sixth and seventh bulleted points (D.I. 185, ¶¶ 425-92) fail, for essentially the same reasons.

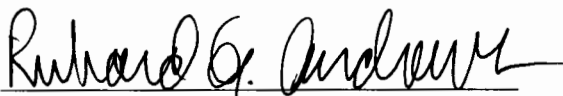
The second individual accused of inequitable conduct is the inventor, Malladi. The allegations against Malladi are the same as the arguments directed at Dr. Weiner, or variations thereof, and are similarly without plausibility.

The third and fourth individuals accused of inequitable conduct are two prosecuting

attorneys. The allegations against them are essentially the same as those against Dr. Weiner, and fail for the same reasons.⁵

Plaintiffs' Motion to Dismiss and/or Strike Perrigo's Inequitable Conduct Counterclaims and Defenses (D.I. 201) is **GRANTED**. Plaintiffs' Motion for an Award of Attorneys' Fees (D.I. 201) is **DENIED**.

IT IS SO ORDERED this 6th day of January 2015.


United States District Judge

⁵ Inasmuch as I do not think Perrigo has alleged a false statement or a failure to disclose a material fact, I do not need to reach Plaintiffs' other arguments for dismissal.